PTO/SB/92 (08-03) Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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oplication No. (if known): 10/719,534

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Information Disclosure Statement (4pp)

Search Report issued in PCT/US97/07577 (3 pp)

Search Report issued in DP 97922668 (2 pp)

PTO/SB/08 (2 pp)

PTO/SB/92 Express Mail Certificate Under 37 CFR §1.10 (1 p)

Costomer No.: 07278 Docket No.: 02591/100B206-US3

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

application of: Anthony H. CINCOTTA et al.

Serial No.: 10/719,534 Art Unit: 1642

Filed: November 21, 2003 Examiner: Gary B. Nickol

For: GROWTH INHIBITION AND ERADICATION OF SOLID TUMORS USING

NEUROENDOCRINE RESETTING THERAPY AND PHOTODYNAMIC

THERAPY

March 12, 2004

#### **INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement is submitted in accordance with 37 C.F.R. 1.97, 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the above-identified application, and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application.

- 1. This IDS should be considered, in accordance with 37 C.F.R. 1.97, as it is filed: (Check one of the boxes A-D)
  - []A. Within three months of the filing date of the above-identified national application or within three months of the entry into the national stage of the above-identified international application.
  - [X] B. before the mailing date of a first office action on the merits, or a first office action after filing a request for continued examination.
  - [] C. after (A) and (B) above, but before the mailing date of a final rejection, a notice of allowance, or any other action that closes prosecution, and Applicants have made the necessary statement in box "i" below or paid the necessary fee in box "ii" below.

(check one of the boxes "i" and "ii" below:)

- [] i. Counsel states that, upon information and belief, each item of information listed herein was either (a) cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS; or (b) was not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of undersigned after making reasonable inquiry, was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.
- [] ii. A check for the fee set forth in 1. 17(p), presently believed to be \$180, is enclosed.
- [] D. after (A), (B) and (C) above, but before payment of the issue fee: Counsel states that, upon information and belief, each item of information listed herein was either (i) cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the IDS; or (ii) was not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the undersigned after making reasonable inquiry, was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.
  - [] i. A check for the fee set forth in 1.17 (p), presently believed to be \$180, is enclosed.
- 2. In accordance with 37 C.F.R. 1.98, this IDS includes a list (e.g., form PTO/SB/08) of all patents, publications, or other information submitted for consideration by the office, either incorporated into this IDS or as an attachment hereto. A copy of each document listed is attached, except as explained below.

(check boxes A, B and/or C and fill in blanks, if appropriate.)

- [] A. Pursuant to the Notice issued by the United States Patent and Trademark Office dated July 11, 2003 waiving the requirements of 37 C.F.R. § 1.98(a)(2)(i), a copy/copies of the United States Patent on PTO/SB08 is/are not being submitted.
- [] B. Document(s) \_\_\_\_\_ is (are) deemed substantially cumulative to document(s) \_\_\_\_\_, and, in accordance with 1.98(c), only a copy of each of the latter documents is enclosed.
- [X] C. Documents 1-53 on the attached PTO/SB/08 were previously cited by or submitted to the Office in the following prior applications, which are relied upon under 35 U.S.C. 120:

Serial No. 09/187,768, filed November 6, 1998, and Serial No. 08/838,079, filed April 15, 1997.

Copies of these documents need not be filed in this application. Applicant requests that these documents be considered and made of record in accordance with 1.98(d). Per 37 CFR 1.98(d).

[] 3. Document	nt(s) are not in the English language. In accordance with
1.98(c), Applicant sta	tes:
<b>[]</b>	An English translation of each document (or of the pertinent portions thereof), or a copy of each corresponding English-language patent or application is enclosed.
[]	A concise explanation of the relevance of document(s) is found in the attached search report (see MPEP ' 609 A(3)x).
[]	A concise explanation of the relevance of document(s) is set forth as follows: [Insert concise explanation of relevance]
[]	A concise explanation of the relevance of document(s) can be found on page(s) of the specification.
[]	A concise explanation of document(s) can be found on the attached sheet.

- 4. No explanation of relevance is necessary for documents in the English language (see MPEP '609 A(3)).
  - [X] 5. Other information being provided for the examiner's consideration follows:
- (A) An International Search Report, dated August 4, 1997, which issued during the prosecution of International Application No. PCT/US97/07577, which corresponds to the present application; and
- (B) An international style Supplementary Search Report, dated October 15, 1999, which issued during the prosecution of European Application No. EP 97922668, which corresponds to the present application.
- 6. In accordance with 37 C.F.R. 1.97(g) and (h), the filing of this IDS should not be construed as a representation that a search has been made or that information cited is, or is considered to be, material to patentability as defined in '1.56 (b), or that any cited document listed or attached is (or constitutes) prior art. Unless other-wise indicated, the date of publication indicated for an item is taken from the face of the item and Applicant reserves the right to prove that the date of publication is in fact different.

Early and favorable consideration is earnestly solicited.

Respectfully submitted,

Mitchell Bernstein, Ph.D.

Registration No. 46,550 Agent for Applicant(s)

DARBY & DARBY P.C. 805 Third Avenue New York, N.Y. 10022 (212) 527-7700

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## **INFORMATION DISCLOSURE** STATEMENT BY APPLICANT

(Use as many sheets as necessary)

1 2 Sheet

Complete if Known			
Application Number	10/719,534		
Filing Date	November 21, 2003		
First Named Inventor	Anthony H. CINCOTTA		
Art Unit	1642		
Examiner Name	Gary B. NICKOL		
Attorney Docket Number	02591/100B206-US3		

	U.S. PATENT DOCUMENTS				
		Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where
	Cite No. <sup>1</sup>				Relevant Passages or Relevant Figures Appear
	1.	3,752,814	08/14/1973	Fluckiger et al.	
	2.	3,752,888	08/14/1973	Fluckiger et al.	
	3.	5,225,433	07/06/1993	Dougherty et al.	
	4.	5,344,832	09/06/1994	Cincotta et al.	
	5.	5,468,755	11/21/1995	Cincotta et al.	
	6.	5,496,803	03/05/1996	Meier et al.	
	7.	5,554,623	09/10/1996	Cincotta et al.	
	8.	5,585,347	12/17/1996	Meier et al.	
	9.	5,792,748	06/1995	Cincotta et al.	
	10.	6,071,914	06/1995	Cincotta et al.	

FOREIGN PATENT DOCUMENTS						
Examiner	Cite	Foreign Patent Document	Publication	Name of Patentee or	Pages, Columns, Lines,	
Initials*	No.1	Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)	Date MM-DD-YYYY	Applicant of Cited Document	Where Relevant Passages or Relevant Figures Appear	
	11.	DE 3 216 869	11/03/1983			
	12.	DE 3 216 870	11/03/1983			

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²	
	13.	Lin, Cancer Cells 3: 437-444 (1991)		
	14.	Cincotta et al., Cancer Res. 54: 1249-1258 (1999)		
	15.	Lengyel et al., Fert. & Steril. 59: 980-987 (1993)		
	16.	Aldeghi et al., Eur. J. Cancer 30A:167-170 (1994)		
	17.	Barnett et al., Postgrad. Med. J. 56:11-14 (1980)		
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	20.	Bartsch et al., Ann. NY Acad. Science 719:502-525 (1994)		
	21.	Chatterjee et al., Medline Abstract no. 90095797 (1989)		
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	27.	Kane et al., Medline Abstract no. 94305357 (1994)		
	28.	Kikuchi et al., Medline Abstract no. 89079088 (1989)		
L	29.	Lengyel et al., Fertility and Sterility 59:980-987 (1993)		

Examiner Date Signature Considered

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Attorney Docket Number	02591/100B206-US3		

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47.	Coppola, A et al., "Augmentation of Photodynamic Effects: The Synergistic Action of Hematoporphyrin and Chlorpromazine," <i>J. Tumor Marker Oncol.</i> 1(3):205-211 (1986)	
48.	Benzo[a]phenothiazinium Photosensitizers: In Vitro Evaluation," <i>Photochem. Photobiol.</i> 46(5)751-758 (1987)	
49.	Cincotta, L. et al., "Photoxicity, Redox Behavior, and Pharmacokinetics of Benzophenoxazine Analogues in EMT-6 Murine Sarcoma Cells," Cancer Research 53(11):2571-2580 (1993)	
50.	Molitch, M.E., Endocrinol. Metab. Clin. North Am. 21(4) (1992) (abstract only)	
51.		
52.	Nagasawa et al., Cancer Research 34:2643-2646 (1974)	
53.	Bergh et al., N. Engl. J. Med. 300(24) (1979) (abstract only)	

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Examiner	Date	
Signature	Considered	

<sup>&</sup>lt;sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.